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09/839,185	04/19/2001	Eduard Daniel Leendert Schmidt	S-30683A	1538

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EXAMINER
MOONAN, FRANCIS P

ART UNIT	PAPER NUMBER
1638	

DATE MAILED: 07/29/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application N . 09/839,185	Applicant(s) SCHMIDT ET AL.	
	Examiner Francis P Moonan	Art Unit 1638	

-- The MAILING DATE of this communication appears n the c ver sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 April 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *19 April 2001* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a)☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 7 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

In response to the restriction requirement of Paper No. 8. applicant elects without traverse in Paper No. 10 filed on 29 April 2002 , Group I, claims 1-14, drawn to a method of increasing the probability of vegetative reproduction in a plant by transgenically expressing a gene whose protein does physically interact with the protein of a somatic embryo receptor kinase (SERK) gene, wherein said gene encodes the sequence comprising SEQ ID NO:2, and the resultant plant.

Claims 1-14 are examined in the Office Action that follows, and the claims are examined to the extent that they are read on an elected Group I.

Priority

Receipt is acknowledged of a certified copy of the United Kingdom 9823098.0 application referred to in the oath or declaration or in an application data sheet, and a claim for foreign priority under 35 U.S.C. 119(b).

Drawings

This application has been filed with informal drawings which are acceptable for examination purposes only. Formal drawings will be required when the application is allowed. See form PTO-948.

Claim Objections

Claims 3-4 and 10-13 are objected to because of the following informalities:

Claim 3 is objected to for the recitation of "14-3-3 type lambda proteins", because the phrase is drawn to a nonelected Group V.

Claims 4 and 10-13 are objected to for the recitation of the terms "SEQID NO:4", or "SEQID NO:6", or "SEQID NO:8", or "SEQID NO:10", or "SEQID NO:12", or "SEQID NO:14", or "SEQID NO:16". The terms are each drawn to a nonelected Group.

Appropriate correction is required.

Claim Rejections - 35 USC § 101 and 112

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 10-12 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Claims 10-12 are broadly drawn to a gene (Claims 10-11); or to a pseudogene or naturally occurring mutation (Claim 12) of a plant.

The gene, as broadly claimed, has the same characteristics and utility as those genes found naturally in plants and therefore does not constitute patentable subject matter. See *American Wood v. Fiber Distintegrating Co.*, 90 U.S. 566 (1974), *American Fruit Growers v. Brogdex Co.*, 283 U.S. 2 (1931), *Funk Brothers Seed Co. v. Kalo Inoculant Co.*, 33 U.S. 127 (1948), *Diamond v. Chakrabarty*, 206 USPQ 193 (1980).

Applicant is advised that amendment by substitution of "A gene" with --An isolated polynucleotide-- on line 1 of Claims 11-12; and by replacement of "A gene" with --An isolated polynucleotide, -- on line 1 of Claim 10, would obviate this rejection. Applicant is further advised that such an amendment would require amendment of Claim 13 to replace "gene" with --polynucleotide--.

Claims 1-9 and 14 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specifically asserted utility or a well established utility.

Claims 1-9 are broadly drawn to method for increasing the probability of vegetative reproduction of a new plant generation comprising transgenically expressing a gene encoding a protein acting in the signal transduction cascade triggered by SERK. Claim 14 is broadly drawn to a plant or plant cell transgenically expressing any gene according to the method of Claim 1.

The SERK-designated proteins of the instant specification have only been disclosed as belonging to a class of evolutionarily related genes of plants referred to as leucine rich repeat (LRR) receptor kinases or LRR receptor-like kinases; with relatedness assessed by sequence homology comparisons.

Only the presumed binding of *Arabidopsis* SERK-designated fusion-proteins to another fusion protein in a yeast two hybrid system assay is disclosed, which comprises protein fusions interacting in a chemically high reducing-environment yeast nucleus, wherein said yeast nucleus does not chemically, physiologically, or cytologically represent a plant cytoplasmic environment where SERK proteins would be localized in plant cells.

Only the structure of a carrot SERK protein is disclosed. The structure of a designated *Arabidopsis* polynucleotide encoding a SERK protein is not disclosed.

Only broadly claimed method transformation steps of plants are disclosed. No specific transgenic plants comprising any specific transgene are disclosed; nor any phenotypic characterization of said transgenic plants by any means of evaluation of alterations of sexual or asexual reproduction, including obligate or facultative apomixis, is disclosed, nor evaluation of methods to determine said phenotypes.

No other morphological, physiological, or biochemical characterization of any SERK, or any SERK signal transduction pathway in any plant is disclosed.

The state of the art at the time of the filing of the instant application is that assignment of a protein to a genetic signal transduction cascade based on an assessment of yeast- two hybrid system properties, or through inference based on homology alone, is insufficient evidence to support a credible claim of a protein acting in a signal transduction pathway. While empirical data is not required for patentability, the state of the art recognizes that a functional assignment obtained by sequence comparisons may categorize a protein or provide a starting point for verifying protein activity, but it does not replace empirical data for determining its activity. Furthermore, although a yeast two-hybrid screen may provide a starting point for determining possible protein-protein interactions in planta, by itself, said interaction in yeast is not a credible or reliable predictor of similar interactions *in planta*. Specifically, Golemis et al (1997. Adjustment of parameters in the yeast two-hybrid system: criteria for detecting physiologically significant protein-protein interactions. Pp 11-28. In, Current Innovations in Molecular Biology: Gene Cloning and Analysis. Horizon Scientific Press.) teach that the yeast two-hybrid system typically identifies genes and proteins encoded by said genes that are "false positives" which have no biological relevance to the "bait" utilized to isolate it (See for example page 25, lines 51-66). Furthermore, Aashland et al (2002. The Yeast Two Hybrid Screen, Version 22 May 2002. Pp. 1-8.) teach that a survey analysis of 100 researcher groups utilizing yeast-two-hybrid system technology, to determine whether the yeast two-hybrid screen identified protein-protein interactions termed "false positives", which produce protein-protein interactions in yeast but not in the native organisms from which the genes used in the technology were derived, resulted in a response from 73 research labs that indicated that a yeast two hybrid system screen was an

unpredictable assay for the determination of in planta protein-protein interactions (See pages 1-8). Aashland et al teach that of the 73 research groups that responded to the survey, that all had discovered some isolated "false positives" by analyzing the native organisms from which the genes used in the yeast-two-hybrid system were derived, which encompassed 101 "bait" plasmids used in yeast two hybrid system screening procedures (See pages 1-8).

Furthermore, the state of the art does not support a specific and credible finding of utility for a Squamosa Binding Protein (SBP) as a modulator of apomictic development, or plant vegetative reproduction; or that any classified SBP protein may credibly be identified as binding to a Squamosa ortholog and functioning as a transcription factor, based on an assessment of gene structural homology or evolutionary relatedness; or that any specific corresponding elements of any LRR-receptor kinase signal transduction pathway had been defined in any plant at the time of Applicant's filing, or at any date since, with the exception of the predictable ability of an LRR-receptor kinase to be capable of autophosphorylation.

Ferrandiz et al (1999. Annu. Rev. Biochem. 68:324-354) specifically teach that the function of an LRR receptor kinase classified on the basis of homology is unpredictable in predicting function, and that no clear model of signal transduction involving the activity of any LRR receptor kinase had been credibly established as of 1999 (See pages 350, line 27 to page 351, line 34).

Cardon et al (1997. The Plant Journal 12(2):367-377) and Cardon et al (1999. Gene 237:91-104) specifically teach, that the state of the art at the time of filing, was that a protein classified on the basis of homology as an Squamosa-binding protein (SPB) transcription factor, is that of seven orthologous *Arabidopsis* SBP classified proteins, designated SBP1 to SBP7, only SPL3 exhibited binding activity to an AP1-1 promoter, in either *in vitro* expression experiments, or in experiments with isolated nuclei and nuclear extracts, and that homology of these proteins is not a substantial and credible determinant for predicting their function (See for example Cardon et al, 1997 on page 369, column 2; and page 374 column 2; and see Cardon et al 1999, on page 91, column 2, page 91; page 95, column 2, lines 4-26; page 97, column 2, lines 16-27; Figures 3-4 on page 97; and page 99, column 1, line 19 to page 103, column 2, line 26). Furthermore, Cardon et al (1997) specifically teach that the *Arabidopsis* AP-1 floral organ identity gene is an ortholog of the *Antirrhinum* Squamosa gene, and that mutations in AP-1 in

Arabidopsis and Squamosa in *Antirrhinum* produce similar phenotypes by producing orthologous floral organ identity-switches during their respective flower development, which do not involve alterations in vegetative reproduction or apomictic development (See page 91). Furthermore, on page 17, lines 30-31 of the instant specification, applicant discloses that the SEQ ID NO: 2 *Arabidopsis* sequence of the instant invention has 100% identity to the SBP *Arabidopsis* ortholog taught by Cardon et al (1999. Gene 237:91-104), which is also designated by Cardon et al (1999) as SBL9. See also the attached STIC Sequence report which teach that the sequence of SEQ ID NO: 1 and SBL9 are identical. Cardon et al (1999) teach that Arabidopsis comprises an evolutionarily-related set of at least 11 SBL genes, as isolated and cloned by hybridization from libraries, or cloning via PCR-based methods (See for example Figs. 3-4 on page 97). Cardon et al (1999) teach that although transgenic expression of SPL3 may elicit a trait of early flowering in *Arabidopsis*, no clear link between SBL3 and AP-1 could be shown *in vivo* (See column 2 on page 102), and that expression of SPL1, SPL2, SPL4, and SPL5 as transgenes result in no detectable alteration in any phenotypic trait (See column 1 on page 103). Cardon et al teach that over 25 evolutionarily-related SBP genes have been identified in all plants (See Fig. 8 on page 101). However, Cardon et al (1999) teach that with the exception of the maize SBP gene LG1, and the *Arabidopsis* SBL3, no other SBP-related gene has been identified as corresponding to any particular plant trait or phenotype (See column 1 on page 103).

It is apparent that extensive further research, not considered to be routine experimentation, would be required by one of skill in the art to know how to use the claimed invention. It has been established in the courts that a utility which requires or constitutes carrying out further research to identify or confirm a "real world" context of use is not a substantial utility (See *Brenner v. Manson*, 383 U.S. 519, 1966). Thus, one of skill in the art would not conclude that the yeast two hybrid system assayed binding of any protein to any LRR receptor kinase, including SERK, would be a specific, substantial, and credible predictor that such an interaction occurred *in planta*; or that said assay would be an indicator of said proteins "acting" in any particular signal transduction cascade leading to vegetative or sexual reproductive alterations, including apomictic reproduction. Applicant's claimed invention is hence not refined to the point where specific benefit exists in its currently available form. As set

forth above, one skilled in the art cannot readily take Applicant's claimed invention and derive immediate benefits from it based on Applicant's disclosure.

Accordingly, the claimed invention lacks a substantial and credible utility and real world use. (See Utility Guidelines published in Federal Register/ Vol 66, No. 4/Friday, January 5, 2001/ Notices; p. 1092-1099; and see MPEP 2107.01-MPEP 2107.02).

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-9 and 14 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claims 1-9 and 14 are rejected under 35 U.S.C. 112, first paragraph, for the reasons as stated in the 35 U.S.C. 101 rejection above. Specifically, since the broadly claimed invention is not supported by either a specifically asserted utility or a well established utility for the reasons of unpredictability and undue experimentation set forth above, one skilled in the art clearly would not know how to **use** the claimed invention as broadly claimed.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 5 and claims dependent theron are rejected under 35 U.S.C. 112, second paragraph as generally narrative, vague, and indefinite, failing to conform with current U.S. practice. Claim 1 is indefinite because it is incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are:

those steps which correspond to vegetative reproduction of a plant. The method only recites a narrative for the activation of a cascade without a method step for making a transgenic plant; or a method step for evaluating an alteration in the vegetative reproduction in a transgenic plant, in relation to the native plant from which the transgenic plant would be produced. Claim 1 is also indefinite because it is incomplete for omitting essential structural cooperative relationships of elements, such omission amounting to a gap between the necessary structural connections. See MPEP § 2172.01. The omitted structural cooperative relationships are: the elements of the "signal transduction cascade". Furthermore, Claim 1 is vague and indefinite for the recitation of "the probability of vegetative reproduction of a new plant generation", because the claim omits and is missing an essential method step of assessment of probability, and it is unclear what degree of probability is determined, and by what means.

Claim 2 is vague and confusing in the recitation of "wherein the encoded protein physically interacts with SERK". The claim is vague and confusing because it is unclear as to whether the claim is intended to refer to a property of interaction in planta, or to a general property of interaction under any set of conditions that are separate and distinct from the *in planta* environment and interaction conditions of Claim 1.

Claims 4 and 10 and claims dependent thereon are rejected as vague and indefinite in the recitation of "having a component sequence". The claim is vague and unclear as to whether the claimed invention is drawn to a componentized sequence of known length and composition conjugated with other componentized sequences of known length and composition; or whether the sequence as claimed is part of an overall sequence composition of undisclosed metes and bounds.

Claim 4 and 10 are vague in the recitation of "which after alignment". The claims are vague as to what measures of algorithmic design, or parameter design, for example allowable gaps in the recited alignment were performed, and fails to set forth the metes and bounds of any particular comparison of sequences that is encompassed by an "alignment" .

Claim 7 is vague in the recitation of "in the vicinity". What is "in the vicinity" is a subjective and arbitrary determination that fails to set forth the metes and bounds of the invention.

Claim 8 is vague and indefinite for the recitation of "the probability of in vitro somatic embryogenesis". The claim is vague and indefinite because the claim omits and is missing an essential method step of assessment of probability, and it is unclear what degree of probability is determined, and by what means.

Claim 9 is vague and confusing in the recitation of "the gene is under control of the SERK gene promoter". The phrase is vague and confusing because a "gene" as recited comprises transcriptional and translational regulatory elements both upstream, downstream, and internal to a coding sequence" in its art-accepted interpretation. Applicant is advised that claim language in which a SEQ ID DNA sequence is recited as operably linked to a specific promoter sequence is language which conforms to art-accepted U.S. Practice.

Claim 12 is vague in the recitation of "known RNA instability motifs". The claim is vague because what is known by any one person as a motif leading to instability is sequence dependent; and what is known by any one person is relative, and fails to set forth the metes and bounds of the invention.

Claim 13 is rejected as vague and indefinite in the recitation of "transgenically expressing". The phrase is not art-recognized.

Claims 1-9 and 13-14 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claims 1-9 are broadly drawn to method for increasing the probability of vegetative reproduction of a new plant generation comprising transgenically expressing a gene encoding a protein acting in the signal transduction cascade triggered by SERK. Claim 14 is broadly drawn to a plant or plant cell transgenically expressing a gene according to Claim 1. Claim 4 is limited to a method with a SERK-interacting protein encoded by SEQ ID NO:2 . Claim 13 is limited to a plant or plant cell comprising a transgene having the nucleotide sequence of SEQ ID NO:1.

Golemis et al (1997. Adjustment of parameters in the yeast two-hybrid system: criteria for detecting physiologically significant protein-protein interactions. Pp. 11-28. In, Current Innovations in Molecular Biology: Gene Cloning and Analysis. Horizon Scientific Press) teach

that essential to the practice of the yeast two hybrid system method are: a specifically constructed yeast two hybrid system "bait" plasmid comprising a DNA sequence insert which would produce a fusion protein in an *E. coli* or yeast assay system; a source of "target" plasmid comprising either a singular specific plasmid comprising an encoded sequence for a second fusion plasmid, or a library of said "target" plasmids; and specific control experiments which verify that the yeast two hybrid system assay most likely represents a protein-protein interaction after expression in transformed yeast or *E. coli* cells that have been transformed with a variety of plasmid combinations. Furthermore, Golemis et al teach that in the absence of proper controls in a yeast two hybrid system assay, the assay is unpredictable in determining native protein-protein interactions in the organisms from which the "bait" and "target" plasmid insert sequences were isolated (See pages 11-25), as stated above.

Aashland et al (2002. The Yeast Two Hybrid Screen, Version 22 May 2002. Pp. 1-8.) teach even when the best available control experiments are performed with yeast two hybrid system assays, that the assay is unpredictable in determining native protein-protein interactions in the organisms from which the "bait" and "target" plasmid insert sequences were isolated (See pages 1-8), as stated above.

Schmidt et al (1997. Development 124:2049-2062), Farrandiz et al (1999. Annu. Rev. Biochem. 68:324-354), and Pai et al (1998. J. Japan Soc. Hort. Sci 67(6):1147-1152) teach that the phenotype elicited by the expression of a leucine-rich repeat (LRR) receptor-like kinase is unpredictable. Schmidt et al teach that a carrot SERK is a leucine-rich repeat (LRR) receptor kinase that most closely resembles *Arabidopsis* Erecta, whose expression alters the apical dominance and shoot growth in *Arabidopsis*, and the tomato Cf-9, whose expression alters the resistance of tomato to disease caused by specific races, strains, or pathovars of the fungus *Cephalosporium fulvum* (See Figure 2a on page 103). Furthermore, Schmidt et al only teach that the carrot SERK steady state RNA levels and expression patterns during in vitro culturing for somatic embryos show particular patterns of expression levels in partially synchronous cultures (See Figure 1), and that as expected from the highly conserved protein kinase domains and subdomains, that *in vitro* translated protein of an isolate carrot SERK gene exhibited autophosphorylation *in vitro*. Pai et al teach the overexpression of a sense and antisense LRR receptor kinase (PRK1) transgene, when expressed in petunia, indicated that PRK1 was

necessary and sufficient for normal male microspore (and pollen) and female unreduced embryo sac development, but had no effect on apomictic or vegetative reproductive development (See pages 1150-1151). Pai et al teach that transgenic plants expressing a PRK-antisense transgene exhibit the traits of both male and female infertility, as the result of aberrant microspores, and abortion of embryo sacs at a 7-nucleii stage (See pages 1150-1151). Furthermore, Ferrandiz et al teach that the function of an LRR receptor kinase classified on the basis of homology is unpredictable in predicting function (See pages 350, line 27 to page 351, line 34). One of skill in the art would know that the phenotypes of transgenic plants of any species of plant, comprising expression of any LRR receptor kinase, would be unpredictable.

Ellerstrom et al (1977. Heriditas 87:107-120), Hanna et al (1987. Crop Sci. 27 :1136-1139), Holm et al (1996. Hereditas 125:77-82), Hovin et al (1976. Crop Sci. 16 :635-638), and de Wet et al (1970. Caryologia 23 :183-87) teach that in the absence of reliable histological, chromosome counting, and karyotyping technique screening assays for the determination of the trait of genetic stabilizing of apomixis; and in the absence of molecular, genetic, physiological, or morphological markers specifically developed for a particular combination of plant genotypes; that the screening, identification, and selection of plants exhibiting a trait of apomixis is unpredictable. See Ellerstrom et al (1977) in the Abstract on page 107; on page 107, column 1, line 1 to column 2, line 20; on page 107, column 2, lines 1-18; in Tables 1-3 on pages 108 and 113; and on page 108, column 1, line 12 to page 118, column 2, line 39; on page 107, column 2, lines 1-18; in Tables 1-3 on pages 108 and 113; and on page 108, column 1, line 12 to page 118, column 2, line 39; and on page 109, column 1, lines 6-54. See Hanna et al on page 1138, column 1, lines 39-47; in Table 1 on page 78; and on page 77, column 1, line 8 to column 2, line 13. See Holm et al teach in Table 1 on page 78; and on page 77, column 1, line 8 to column 2, line 13. See Hovin et al on page 638, column 2, lines 16-26. See de Wet in the Abstract on page 183; in Table 1 on page 184; and on page 184, line 1 to page 186, line 17.

Applicant fails to provide guidance for the sequence of any particular SERK sequence for the "bait" insert, essential to the practice of the invention. Applicants fails to disclose any SEQ ID NO. for any *Arabidopsis* SERK. The instant specification only discloses an Arabidopsis SERK ortholog, but fails to identify any particular SERK sequence that would be used to make a bait or identify the insert of the "bait sequence" as the ortholog of the originally carrot SERK

taught by Schmidt et al. In light of the disclosure, one of skill in the art would not know what criteria were utilized to characterize the essential *Arabidopsis* sequence as SERK, beyond the broader designation of the essential sequence as a member of a broader and more functionally diverse group of the LLR-receptor kinases.

Applicant fails to provide guidance for a reliable yeast two hybrid system screen and the making of a plant with the claimed protein-protein interactions. Applicant fails to disclose any control plasmid combinations that would be required by one of skill in the art to evaluate the claimed method; and applicant fails to provide any guidance for any means for either the evaluation of the claimed protein-protein interactions, nor the guidance for the evaluation of the claimed signal transduction pathway; nor the method steps by which apomictic, or sexual versus asexual reproductive development would be evaluated. Applicant for example fails to disclose any anti-SERK or anti-SBP antibodies which would be utilized to perform immunoprecipitation with plant extracts or *in situs* to provide an evaluation assay for protein-protein *in planta* interactions, which would allow one of skill in the art to make the invention as broadly claimed.

Given the breadth of the claims, the state of the art, the unpredictability, and lack of guidance, one of ordinary skill in the art would be required to develop a multitude of constructs, isolate a multitude of genes, develop a multitude of reagents and methods to identify, evaluate and characterize a multitude of signal transduction pathways comprising a multitude of expressed genes and proteins and protein-protein interactions, to **make** the invention as broadly claimed.

Claims 1-9 and 12-14 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

Claims 1-9 are broadly drawn to method for increasing the probability of vegetative reproduction of a new plant generation comprising transgenically expressing any gene encoding a protein acting in the signal transduction cascade triggered by SERK. Claim 14 is broadly drawn to a plant or plant cell transgenically expressing a gene according to Claim 1. Claim 4 is limited to a method with a SERK-interacting protein encoded by SEQ ID NO:2 . Claim 12 is

drawn to any modified nucleotide sequence of any nucleotide sequence that encodes an amino acid sequence of SEQ ID NO:2, wherein modifications include a deletion, or modifications of alternative codon substitutions in SEQ ID NO:2.

The Federal Circuit has recently clarified the application of the written description requirement. The court stated that a written description of an invention "requires a precise definition, such as by structure, formula, [or] chemical name, of the claimed subject matter sufficient to distinguish it from other materials." University of California V. Eli Lilly and Co., 119 F.3d 1559, 1568; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997).

The instant specification only provides guidance for transgenes with a nucleotide sequence of SEQ ID NO:1, encoding a peptide with a sequence of SEQ ID NO:2.

No transgene with any particular modification is provided, nor are any transgenic plant, nor any transgenic plant with a trait of increased apomictic or vegetative reproductive development is provided.

Since the essential transgenes of the broadly claimed methods are not described, the methods and the transgenic plants are not adequately described.

Hence, the specification does not provide an adequate written description of the broadly claimed genus.

See University of California v. Eli Lilly and Co., 43 USPQ2d 1398 (Fed. Cir. 1997) which teach that the disclosure of a process for obtaining cDNA from a particular organism and the description of the encoded protein fail to provide an adequate written description of the actual cDNA from that organism which would encode the protein from that organism, despite the disclosure of a cDNA encoding that protein from another organism.

See Amgen Inc. v. Chugai Pharmaceutical Co. Ltd., 18 USPQ 2d 1016 at 1021 and 1027, (Fed. Cir. 1991) at page 1021, where it is taught that a gene (or promoter) is not reduced to practice until the inventor can define it by "its physical or chemical properties" (e.g. a DNA sequence).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-2, 8-9 and 14 are rejected under 35 U.S.C 102(b) as anticipated by Schmidt et al (1997. Development 124:2049-2062) in light of Shah et al (2001. J. Molec. Biol. 309(3):641-55).

The claims are broadly drawn to method for increasing the probability of vegetative reproduction of a new plant generation comprising transgenically expressing a transgene encoding a protein "acting" in the signal transduction cascade triggered by SERK, that interacts with SERK. Claim 2 is limited to a protein that physically interacts with "SERK". The "SERK" of the claims is interpreted to included SERK proteins or SERK genes. The "acting" in a SERK pathway is interpreted in the broadest and most reasonable interpretation to include any genetic or biochemical pathway or activity involving SERK.

Schmidt et al teach for example in column 1 on page 2059 that a SERK promoter comprising translational elements upstream of the SERK coding region were utilized to construct a transgene for the expression of a luciferase reporter protein under the regulation of SERK 5' sequences; the transformation of carrot tissue cultures and somatic embryos and plantlets with said construct; and the evaluation of luciferase expression patterns during somatic embryo and plantlet development *in vitro*.

Shah et al teach that an inherent property of a leucine rich repeat (LRR) receptor kinase is its ability to autophosphorylate via homodimerization or oligomerization, and that a SERK protein homodimerizes either natively, or when expressed as a transgene (See the Abstract on page 641; and pages 641-651).

Claims 3-7 and 10-13 are deemed free of the prior art, due to the failure of the prior art to teach or suggest a method for increasing the probability of vegetative reproduction in a plant by transgenically expressing a Squamosa Binding Protein that physically interacts with a Somatic

Embryogenesis Receptor Kinase protein; a protein with the peptide sequence of SEQ ID NO: 2 that is encoded by the genes having the nucleotide sequence of SEQ ID NO:1; and transgenic plants or plant cells made by said method.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Francis Moonan, whose telephone number is (703) 605-1201. The examiner can normally be reached on Monday through Friday 9:00 AM to 5:00 PM (E.S.T.)

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached at (703) 306-3218. The fax phone number for this Group is (703) 308-4315. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989).

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Francis Moonan, Ph. D.
19 July 2002

DAVID T. FOX
PRIMARY EXAMINER
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